

REMARKS

The Office action dated November 19, 2003 is acknowledged. Claims 13 and 15-28 are pending in the instant application and have been rejected by the present Office action. By the present response, claims 13 and 15-25 have been amended and claims 26-28 have been deleted. Claim 13 has been amended to more accurately describe the method of the present invention and better illustrates its inventiveness. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

Rejection of Claims 25-28 under 35 U.S.C. 112, second paragraph

Claims 25-28 have been rejected under 35 U.S.C., second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, the Examiner states that the limitations “applying at least two overlying pigmented layers” (emphasis added by Examiner) and “to visualize the at least two underlying pigmented color layers” (emphasis added by Examiner) are directly contradicting.

The applicant respectfully disagrees with this conclusion and submits that both terms are correctly used in their present form. The subject matter of claim 25 concerns the material layer to be inscribed, wherein the material layer is overlaid with at least two pigmented layers. Selected portions of either one or both of these two pigmented layers may be ablated (i.e., disintegrated) by laser beam inscription. Due to the ablation of the

selected portion, the pigmented layer underneath the pigmented layer that was exposed to the laser beam becomes visible in the ablated portion. Hence, the intermediate pigmented layer underlies the uppermost pigmented layer and the material layer to be inscribed underlies both pigmented layers. Therefore, the applicant submits that claim 25 is correct in its present form and respectfully requests that this rejection be withdrawn.

Regarding the rejections to claims 26, 27 and 28, applicant points out that all three claims have been deleted and so this rejection is no longer germane as it pertains to these claims.

Claim Objections

The Examiner has objected to claim 13 because of the following informality: “the device” on line 11 should read – the sheet-like active agent-containing therapeutic system--, since “the device” would refer to the laser beam emission device, which would not make sense. Applicant has amended this claim according to the Examiner’s suggestion. Therefore, it is respectfully requested that this objection be withdrawn.

Rejection of Claims 13 & 15-28 under 35 U.S.C. 103(a)

Claims 26-28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,831,661 (Tabuchi et al.) in view of WO 97/44196 (Clement) in view of U.S. Patent No. 5,151,572 (Jack). As previously mentioned, the applicant has deleted claims 26-28. Therefore, this rejection is no longer applicable.

Claims 13, 15-22 and 25 are rejected under 35 U.S.C. 103(a) as being

unpatentable over U.S. Patent No. 5,831,661 (Tabuchi et al.) in view of WO 97/44196 (Clement) and the Applicant's Acknowledged Prior Art (AAPA). The Examiner states in the Office action that Tabuchi et al. discloses a device and method for toner-free inscription, e.g., by ablation, of a sheet-like adhesive system comprising placing the sheet-like adhesive system with the adhesive side facing a support position, guiding the laser emission onto the sheet-like adhesive system, and controlling the intensity and penetration depth of the laser beam according to the material properties of the sheet-like adhesive system in such a way that the laser beam does not penetrate far enough into the sheet-like adhesive system and preventing a detrimental influence on the adhesive.

The Examiner states that Tabuchi et al. fails to teach the guidance of the laser beam being performed by a program of a manually operable central control unit, the adhesive containing active therapeutic agent, and the active agent-containing therapeutic system being in the form of a plaster.

The Examiner relies on Clement, which the Examiner states teaches a device and method for forming visible images by laser radiation with the energy as well as the depth of penetration of the laser beam being carefully programmed and/or adjusted such that only selective overlying layers are ablated at the depth of the selected layer without affecting further layers, the overlying layers being colored layers so as to selectively reveal different layers.

The Examiner further states that AAPA suggests the needs for sheet-like active agent-containing therapeutic systems, which includes plaster, to have useful information inscribed onto the material.

It is the Examiner's position that it would have been obvious to one skilled in the art to modify the teaching of Tabuchi et al. to include the programmable control unit as taught by Clement to inscribe information onto the sheet-like adhesive system containing therapeutic active agent as suggested by AAPA, with the motivation being to provide the flexibility and automation to the laser-inscribing device to controllably perform the ablation of the desired layer within the sheet-like adhesive system. The Examiner also states that Tabuchi et al. further teaches that the underlying colored layer can have a multiple layer construction.

Claims 23 and 24 have been rejected as being unpatentable over Tabuchi et al. in view of Clement and AAPA, as applied to claims 13 and 22 above, and further in view of Jack.

According to the Examiner, the modified device of Tabuchi et al. discloses all the basic limitations of the claimed invention except for the programmable central control unit including a keyboard and accepting transferred data. The Examiner states that Jack discloses a method and apparatus for making a stencil for etching glass using a laser beam to cut through the thin stencil template from a label, the apparatus including a host computer with a user input device (e.g., a keyboard) and a laser interface card such that the parameters of the laser beam are controlled based on a user interface control software stored in the host computer.

It is the Examiner's position that it would have been obvious at the time the invention was made to one skilled in the art to incorporate the user interface control software as taught by Jack in the modified device of Tabuchi et al., with the motivation to

provide a consistent, repeatable process of inscribing information.

Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references when combined must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure (M.P.E.P. Sec. 706.02 (j)). It is the Applicant's contention that even if one skilled in the art were to combine the teachings of the aforementioned references as the Examiner suggests, there would still not be a reasonable expectation of success. Moreover, it is the applicant's position that there would not be any motivation for one skilled in the art to even combine the aforementioned references in order to obtain the present invention in the first place. Therefore, based on the following arguments, the applicant respectfully requests that this rejection be withdrawn.

The applicant first points out that toner-free inscription techniques by means of a movably guided laser beam are known, as already pointed out in paragraph 12 of the present specification, or as mentioned in Tabuchi et al. (col. 1, lines 5-36). However, applicant respectfully notes that such inscription technique was thus far only used for inscribing metal substrates or comparatively thick layers of plastic. In the present claims, the material to be inscribed is a sheet-like (emphasis added) active agent-containing system having a material layer to be inscribed – it is not a metal or a thick plastic layer.

The toner-free inscription technique utilizing a movably guided laser beam ablates selected portions of the layer and thereby causes high temperatures which affect the regions located nearby. Therefore, the applicant submits that it was never before considered in the relevant art that such a technique could be successfully used to inscribe transdermal therapeutic systems which are very thin substrates, especially when compared to the metal substrates and plastic layers thus far inscribed by this technique. It was assumed in the art that the high temperature during ablation of the portion of a layer would cause a perforation of the backing layer, which is impermeable to the active ingredient(s) of the transdermal therapeutic system (and must remain this way) and/or would cause degradation of the active ingredient(s) contained in the transdermal therapeutic system. In addition, it was thought that the ablation could affect the pressure-sensitive adhesive such that the adhesive ability of the system would be significantly impaired. It is the applicant's position that the present invention defies the conventional thinking in the art and has overcome each of the aforementioned theories and that the toner-free inscription by a movably guided laser beam can be employed for inscribing transdermal therapeutic systems, as set forth in the present application.

With reference to Tabuchi et al., the applicant submits that the patent fails to even mention transdermal therapeutic systems as a device that can be inscribed by a toner-free inscription technique. Moreover, the reference fails to teach the guidance of the laser beam employed with the present invention as well as a program of a manually operable control unit.

Clement concerns image production by ablation of selected portions of layers by a

laser. However, applicant points out that this reference also fails to teach or mention transdermal therapeutic systems as a device that can be inscribed by a toner-free inscription technique. Moreover, Clement fails to teach the programmable control unit of the present invention. Further still, Clement does not teach or suggest how the problem that is associated with the generation of heat during ablation may be overcome such that the inscription technique might not cause the aforementioned problems that were believed to render this technique unsuitable for inscribing transdermal therapeutic systems.

Clement states that the thickness of the various layers on the substrate is limited by the accuracy of the laser beam (page 4, 3rd paragraph), i.e., the layers may not be too thin, but have to have at least a certain thickness. The reference states in part:

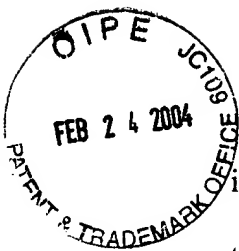
“The thinness of the coat will be limited by the accuracy of the laser beam...”).

To the contrary, the transdermal therapeutic system used with the present invention is a thin object having thin polymer layers (paragraph 13 of the present specification). The applicant respectfully submits that one skilled in the art would clearly infer from the teaching of Clement that the method described therein would not be suitable for inscribing transdermal therapeutic systems having thin polymer layers. Moreover, even if one skilled in the art were to employ a transdermal therapeutic system to be inscribed with the method described in Clement, he or she would clearly not expect that the transdermal therapeutic system would remain unaffected in a negative manner.

Therefore, it is the applicant's position that even the combination of Tabuchi et al. with Clement fails to overcome the prejudice that toner-free laser inscription may not be utilized for labeling transdermal therapeutic systems.

Referring now to Jack, the patent teaches the control unit, but concerns the labeling of a layer of polyester that can withstand a harsh environment. Jack further indicates that all layers of the stencil template are ablated by the laser beam (Figs. 4 and 5). It is the applicant's position that Jack does not teach or suggest that the intensity and penetration depth of the laser beam can be controlled such that a detrimental influence on the backing layer and/or active ingredient-containing layer, which are underlying the material layer to be inscribed, can be avoided. Therefore, Jack, as well as any of the alleged AAPA, fail to make up for any of the aforementioned deficiencies of Tabuchi et al. or Clement and the inclusion therewith fails to render the present invention obvious.

In summary, the applicant submits that even if the combination of the cited references, as applied to claims 13 and 15-25, teaches a method of using a toner-free inscription by a movably guided laser beam emission device wherein the laser beam emission device is guided by a program of a manually operable central control unit as the Examiner states, the combination fails to teach, suggest or indicate that the intensity and penetration depth of the laser beam may be controlled precisely enough such that this method could be applied to inscribing transdermal therapeutic systems which consist of comparatively thin layers. As such, the applicant submits that one skilled in the art would have absolutely no motivation to combine the teachings of these references in an attempt to inscribe or label a transdermal therapeutic system by a toner-free inscription technique, and even if one skilled were to do so, would have absolutely no reasonable expectation of success. Therefore, it is respectfully submitted that this rejection be withdrawn.

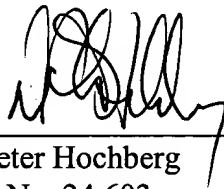


Conclusion

For the foregoing reasons, it is believed that the present application as amended is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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